K080168

MAY 16 2008

5.0 510(k) Summary

Submitter:	Neuro Diagnostic Devices, Inc.
Contact Person:	Frederick J. Fritz, CEO, 215-966-6104 (telephone) 215-966-6001(fax)
Date Prepared:	01/18/2008
Trade Name:	ShuntCheck
Classification:	Class II Central Nervous System Fluid Shunt and Components 21 CFR 882.5550
Product Code:	JXG
Predicate Device(s):	The subject device is equivalent to the following devices: ShuntCheck (version 1.1) (K040021)
Device Description:	ShuntCheck is a non-invasive device which detects flow in a CSF shunt via transcutaneous thermal convection. The device consists of a single use disposable thermosensor array patch which is connected to a handheld "biodisplay" unit. The shunt is cooled transcutaneously by placing ice over the shunt cephalic to the thermosensor. The thermosensor array patch, which is placed on the skin over the shunt "downstream" of the ice, reads the change in skin temperature over the shunt as cooled fluid flows downstream and also at a nearby control location. Data is captured in the biodisplay unit. If the device detects a characteristic downstream transcutaneous temperature dip, the biodisplay reports "flow confirmed". If no temperature dip is detected, the unit reports "flow not confirmed"
Intended Use:	ShuntCheck is an aid to the detection of flow in implanted cerebrospinal fluid (CSF) shunts. ShuntCheck cannot alone diagnose CSF shunt function or malfunction. The clinical diagnosis of CSF shunt function or malfunction, incorporating the flow information from ShuntCheck, should be made only by a qualified neurosurgeon.
Functional and Safety Testing:	To verify that device design meets the functional and performance requirements, each device was submitted to bench testing and performance verification to confirm accuracy when reading resistances (thermistor input simulation) and the expected temperature output displayed by the device software. To verify the functionality of the device, three animal studies were conducted. In the first study, the device was found to be substantially equivalent to the predicate device, the second study, the device was able to detect flow rates (ml/hr), and the third study supported the indication for use change. To verify that device design meets its safety requirements, a representative sample of the device has been subjected safety testing in accordance with IEC 60601-1, IEC 60601-1-4, and IEC 60601-1-2.
Conclusion:	Neuro Diagnostic Devices, Inc. believes the ShuntCheck v2.2 to be substantially equivalent to the predicate device ShuntCheck (v1.0). This conclusion is based upon the both devices' similarities in principles of operation, technology, materials, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Neuro Diagnostic Devices
% Mr. Frederick J. Fritz
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Trevose, Pennsylvania 19053

MAY 16 2008

Re: K080168
Trade/Device Name: ShuntCheck-CSF Shunt Flow Detector
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: May 8, 2008
Received: May 12, 2008

Dear Mr. Fritz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080168

4.0 Indications for Use Statement

Device Name: ShuntCheck—CSF Shunt Flow Detector

ShuntCheck is an aid to the detection of flow in implanted cerebrospinal fluid (CSF) shunts. ShuntCheck cannot alone diagnose CSF shunt function or malfunction. The clinical diagnosis of CSF shunt function or malfunction, incorporating the flow information from ShuntCheck, should be made only by a qualified neurosurgeon.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MXN

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080168